AFS # 42-077-00181

B|BRAUN

July 27, 2015

Mr. Mark Wejkszner
Pennsylvania Department of Environmental Protection
2 Public Square
Wilkes-Barre, PA 18711-0790

Enforcement Programs Section (3AT 13)
USEPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029

RECEIVED
JUL 29 2015
Air Protection Division

Re: Submittal of 40 CFR Part 63.10(e)(3)(i) and (vi)
Summary Report – Excess Emissions and CMS Performance Report
For Units Subject to 40 CFR Part 63, Subpart O
For the period of Jan. 1, through June 30, 2015
B. Braun Medical, Inc., Allentown, Pennsylvania

Dear Sirs:

B. Braun Medical Inc. (B. Braun) operates a surgical and medical instrument apparatus manufacturing facility in Allentown, Pennsylvania. The B. Braun facility operates pursuant to the permit application shield provisions of Title V Operating Permit Number 39-00055, which was issued on January 13, 2010 and expired on January 13, 2015. A timely and complete Title V Renewal Application was submitted on July 9, 2014.

As required under the NESHAP for Ethylene Oxide Emission Standards for Sterilization Facilities (40 CFR Part 63, Subpart O), B. Braun Medical, Inc. (B. Braun) is submitting the attached completed semi-annual summary report in accordance with the requirements of 40 CFR 63.366 and 40 CFR 63.10(e)(3)(i) and (vi). As detailed at §63.10(e)(3)(vii), the total duration of excess emissions or process control system parameter exceedences for the reporting period was less than 1 percent of the total operating time and the CMS downtime for the reporting period was less than 5 percent of the total operating time for the reporting period. Therefore, the full excess emissions and CMS performance reports are not required to be submitted for this reporting period.

If you have any questions or require additional information please do not hesitate to contact me at (610) 596-2584.

Sincerely,

David R. Lauer
Environmental Health and Safety Manager, PA Operations

cc: Enf. Programs Sec.
Ryan Johnson – B. Braun Medical, Inc.
Lindsey W. Kroos – All4 Inc.

SUMMARY REPORT –EXCESS EMISSIONS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE

1.0 Name and Address (physical location) of the Source (40 CFR 63.10(e)(3)(vi)(A)):

B. Braun Medical, Inc.
901 Marcon Blvd.
Allentown, PA 18109

2.0 Identification of Each HAP Monitored at the Source (40 CFR 63.10(e)(3)(vi)(B)):

40 CFR Part 63, Subpart O requires control of ethylene oxide. Direct emission monitoring is not mandatory for ethylene oxide regulated in the standard. As a result, Continuous Parametric Monitoring Systems (CPMS) are specified in the standard to be used as a surrogate for measurement of HAPs. The following table describes the regulated HAPs, along with the required monitoring variable surrogates:

TABLE 2.1: REGULATED HAPS AND ASSOCIATED PARAMETRIC MONITORING VARIABLES

HAP or Other Requirement	Monitored Variables	Citation	Type of Monitoring System
Ethylene Oxide	Ethylene Glycol Concentration or Scrubber Tank Level	63.364(b)	CPMS
	Oxidation Temperature	63.364(c)	CPMS

3.0 Reporting Period (40 CFR 63.10(e)(3)(vi)(C)):

The reporting period covered by this report is from January 1 through June 30, 2015.

4.0 Description of Process Units (40 CFR 63.10(e)(3)(vi)(D)):

B. Braun is located in Allentown, Pennsylvania in Lehigh County. The Allentown facility manufactures surgical and medical instruments that are sterilized during the manufacturing process. Aside from ancillary equipment regulated by the facility's TVOP, and other small insignificant sources, the manufacturing process itself is not a source of air emissions. The sterilization procedure utilizes ethylene oxide (ETO) within a sterilization chamber. B. Braun maintains eight (8) ETO sterilization chambers (Units 101 – 108), which operate on a batch-cycle basis. From each sterilization chamber, the sterilized devices are directed to a common aeration chamber or room (Unit 110). The sterilization chambers and the aeration chamber are regulated by 40 CFR Part 63, Subpart O (Ethylene Oxide Emission Standards for Sterilization Facilities) and vented to emissions control equipment. Each sterilization chamber is equipped with a vacuum pump. During the course of each cycle, the vacuum pump pulls the gas stream containing ETO from the sterilization chamber to a common Deoxx unit, which employs a wet scrubbing technique for treatment of ETO emissions and achieves a 99% emission reduction. Once the majority of

the gas stream has been sent to the Deoxx unit, a small amount of residual, low concentration ETO gas is vented from the rear chamber exhaust vent of each sterilizer and exhausted to atmosphere through a common stack in accordance with 40 CFR §63.362(a). ETO emissions from the aeration chamber are routed to the Donaldson Catalytic Oxidizer, which utilizes a catalyst in conjunction with oxidation to control ETO emissions and achieves a 99% emission reduction or maintains an outlet ETO concentration of less than or equal to 1 ppmv in accordance with 40 CFR §63.362(d).

5.0 Emission and Operating Parameter Limitations Specified in Standard (40 CFR 63.10(e)(3)(vi)(E)):

The applicable emission limitations for sterilization facilities are detailed in 40 CFR 63.362 and are provided in Table 5.1 below.

TABLE 5.1: SUBPART O STANDARDS FOR B. BRAUN

Pollutant	Limit
Ethylene Oxide (Sterilization Chamber Vent)	99% emissions reduction
Ethylene Oxide (Aeration Room Vent)	99% emissions reduction or 1 ppmv, whichever is less stringent

The operating parameters required to be established under the Subpart O MACT standards are detailed at 40 CFR 63.364. The limitations for these parameters are required to be established during the performance testing in accordance with the requirements at 40 CFR 63.365 and the site specific performance test plan.

6.0 Monitoring Equipment Manufacturer and Model Number (40 CFR 63.10(e)(3)(vi)(F)):

Refer to Table 6.1 and Table 6.2 for the monitoring equipment manufacturer and model number.

TABLE 6.1: DEOXX UNIT MONITORING EQUIPMENT MANUFACTURER, MODEL NUMBER, AND LATEST CERTIFICATION DATE

Monitored Variables	Equipment Manufacturer	Model Number	Date of Last CMS Audit or Certification
Ethylene Glycol Concentration	Contract laboratory service	N/A	June, 2015
Scrubber Liquor Level	In house measurement	N/A	June, 2015

TABLE 6.2: DONALDSON CATALYTIC OXIDIZER MONITORING EQUIPMENT MANUFACTURER, MODEL NUMBER, AND LATEST CERTIFICATION DATE

Monitored Variables	Equipment Manufacturer	Model Number	Date of Last CMS Audit or Certification
Oxidation Temperature	Wonderware Software System*	N/A	March, 2015

**The oxidation temperature is measured by a Minco thermocouple that is wired to an Allen Bradley PLC. This PLC input signal value is available for display on the Wonderware InTouch operator screens and within the Wonderware InSQL historian system.*

7.0 Date of Latest CMS Certification or Audit (40 CFR 63.10(e)(3)(vi)(G)):

Please refer to Tables 6.1 and 6.2 for the date of the latest CMS certification or audit.

8.0 Total Operating Time for Each Source (40 CFR 63.10(e)(3)(vi)(H)):

Please refer to the attached emission data (Attachment 1) and CMS performance summaries (Attachment 2).

9.0 Emission Data Summary (40 CFR 63.10(e)(3)(vi)(I)):

The emission data summary for this reporting period is provided in Attachment 1 of this report.

10.0 CMS Performance Summary (40 CFR 63.10(e)(3)(vi)(J)):

The CMS performance summary for this reporting period is provided in Attachment 2 of this report.

11.0 Description of Changes in CMS, Processes or Controls Since Previous Reporting Period (40 CFR 63.10(e)(3)(vi)(K)):

No changes in the CMS, process, or controls have occurred since the previous reporting period.

12.0 Certification and Report Date (40 CFR 63.10(e)(3)(vi)(L) and (M)):

I certify, based on a reasonable inquiry of the persons responsible for preparing this semi-annual report that the information provided is, to the best of my knowledge and belief true, accurate, and complete.

Rex Boland
Vice President/General Manager, PA Operations

Report Date: 7-28-15

Attachment 1
Summary of Excess Emissions

Donaldson Catalytic Oxidizer Unit (Aeration Room Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Exceedence Summary for Reporting Period: 01/1/2015-6/30/2015

Attachment # 1

Donaldson Catalytic Oxidizer Unit Source Operating Time = 260459 [minutes]				Excess Emissions Summary							
Monitored Variable	Limit	Averaging Time		Startup or Shutdown (min)	Control Equipment Malfunction (min)	Process Equipment Malfunction (min)	Other Known Cause (min)	Other Unknown Cause (min)	Total Duration of Excess Emissions (min)	% Excess [a,b] Emissions	Is the % Excess Emissions Greater than 1%?
Minimum Oxidation Temperature	253/258 deg F	15-minute values or shorter, compute and record 24-hour average, when catalytic oxidizer is operated	Duration of Events Where SSM Plan Was Followed	N/A	N/A	N/A	N/A	N/A	N/A		
			Duration of Events Where SSM Plan Was Not Followed	N/A	N/A	N/A	N/A	N/A	N/A	0.00	NO
			Duration of Exceedences Not a Result of a Startup, Shutdown, or Malfunction Event						0		

[a] Excursions caused by Malfunction events are not counted toward the Excess Emissions total duration and 1% full Excess Emission Report threshold level as the limits do not apply during Malfunction events [63.362(b)]

[b] Per §63.10(e)(3)(vii) excess emissions and monitor downtime was calculated based on the total duration of excess emissions or monitor downtime per the total control equipment operating time during the reporting period.

Donaldson Catalytic Oxidizer Unit Operating Time (minutes per semi-annual time period): 260,459

DEOXX Unit (Sterilization Chamber Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Exceedence Summary for Reporting Period: 01/1/2015-6/30/2015

Attachment # 1

DEOXX Unit Source Operating Time = 260040 [minutes]				Excess Emissions Summary							
Monitored Variable	Limit	Averaging Time		Startup or Shutdown (min)	Control Equipment Malfunction (min)	Process Equipment Malfunction (min)	Other Known Cause (min)	Other Unknown Cause (min)	Total Duration of Excess Emissions (min)	% Excess [a,b] Emissions	Is the % Excess Emissions Greater than 1%?
Maximum Scrubber Liquor Level	126 inches	once per week, when scrubber is operated	Duration of Events Where SSM Plan Was Followed	N/A	N/A	N/A	N/A	N/A	N/A		
			Duration of Events Where SSM Plan Was Not Followed	N/A	N/A	N/A	N/A	N/A	N/A	0.00	NO
			Duration of Exceedences Not a Result of a Startup, Shutdown, or Malfunction Event						0		

[a] Excursions caused by Malfunction events are not counted toward the Excess Emissions total duration and 1% full Excess Emission Report threshold level as the limits do not apply during Malfunction events [63.362(b)]

[b] Per §63.10(e)(3)(vii) excess emissions and monitor downtime was calculated based on the total duration of excess emissions or monitor downtime per the total control equipment operating time during the reporting period.

DEOXX Unit Operating Time

(minutes per semi-annual time period): 260,040

Attachment 2
CMS Performance Summaries

Donaldson Catalytic Oxidizer Unit (Aeration Room Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Monitor Performance Summary for Reporting Period: 01/1/2015-6/30/2015

Attachment # 2

Donaldson Catalytic Oxidizer Unit Source Operating Time = 260459 [minutes]			CMS Downtime Summary							
Monitored Variable	Limit	Averaging Time	Monitoring Equipment Malfunctions (min)	Non-Monitoring Equipment Malfunctions (min)	"Non-[a] Routine" QA/QC Calibrations (min)	Other Known Causes (min)	Other Unknown Causes (min)	Total Duration of CMS Downtime (min)	% CMS Downtime	Is the % Excess Emissions Greater than 5%?
Minimum Oxidation Temperature	253/258 deg F	15-minute values or shorter, compute and record 24-hour average, when catalytic oxidizer is operated	0	0	0	0	0	0	0.00	NO

[a] "Routine calibrations" is defined as normal zero and high level checks. These periods are not included in CMS downtime pursuant to 40 CFR 63.10(c)(5) and EPA's MACT reporting guidance (August 2, 2002 Version).

Donaldson Catalytic Oxidizer Unit Operating Time
(minutes per semi-annual time period): 260,459

DEOXX Unit (Sterilization Chamber Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Monitor Performance Summary for Reporting Period: 01/1/2015-6/30/2015

Attachment # 2

DEOXX Unit Source C17Operating Time = 260040 [minutes]			CMS Downtime Summary							
Monitored Variable	Limit	Averaging Time	Monitoring Equipment Malfunctions (min)	Non-Monitoring Equipment Malfunctions (min)	"Non-[a] Routine" QA/QC Calibrations (min)	Other Known Causes (min)	Other Unknown Causes (min)	Total Duration of CMS Downtime (min)	% CMS Downtime	Is the % Excess Emissions Greater than 5%?
Maximum Scrubber Liquor Level	126 inches	once per week, when scrubber is operated	0	0	0	0	0	0	0.00	NO

[a] "Routine calibrations" is defined as normal zero and high level checks. These periods are not included in CMS downtime pursuant to 40 CFR 63.10(c)(5) and EPA's MACT reporting guidance (August 2, 2002 Version).

DEOXX Unit Operating Time
(minutes per semi-annual time period): 260,040